No. 22,102

IN THE

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

HARRY SUGARMAN,

Appellant,

vs.

JACK B. FORBRAGD, et al.,

Appellee.

APPELLANT'S OPENING BRIEF

Appeal to Review Judgment of the
United States District Court for
the Northern District of California

GEORGE McKRAY and
SHELDON I. BALMAN
Fox Plaza, Suite 906
Market at Polk
San Francisco, Calif. 94102

Attorneys for Appellant.

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BRIEF FOR PETITIONER

This case is before the Court on appeal to review judgment of the United States District Court for the Northern District of California.

OPINION BELOW

The memorandum opinion of the United States District Court (IR. 98-124) is reported at 267 F. Supp. 817 (1967).

JURISDICTION

This is an interlocutory appeal from an order entered on May 16, 1967, by the United States District Court for the Northern District of California, dismissing Harry Sugarman's petition for a Writ of Mandatory Injunction (IR. 125-126). The underlying action was brought by the petitioner to compel

the Food and Drug Officers to allow reconditioned coffee beans to be used in the production of blended coffee in the United States under the authority of Section 10 of the *Administrative Procedure Act*, specifically 5 U.S.C. 701(e) (formerly 1009(e)). The district court's jurisdiction was invoked under 28 U.S.C. 1361 (IR. 1-7 including Pet. Exh. "A"-"O"). The petitioner, on June 30, 1967, filed in the district court a timely Notice of Appeal under 28 U.S.C. 2107 (IR. 127). This Court's jurisdiction accordingly rests upon 28 U.S.C. 1291.

STATUTES AND REGULATIONS INVOLVED

The pertinent provisions of the *Administrative Procedure Act* (60 Stat 243 (1946)) as amended, 5 U.S.C. §§552-558, 701-706; §§801, 701 and 304(d) of the *Federal Food, Drug and Cosmetic Act* (52 Stat. 1050, 1055 (1938) as amended; 21 U.S.C. 381, 371, 334(d); and §§ 1.318-1.320, and 4.1(c) of the *Regulations for the Enforcement of the Federal Food, Drug and Cosmetic Act* (20 F.R. 9539, 9554 (1955) as amended), and 21 C.F.R. §§ 1.318-1.320, 4.1(c) are set forth in the Appendix to this Brief.

QUESTIONS PRESENTED

1. Whether governmental determinations on the admissibility of imports are subject to judicial review, either by trial de novo or under the Administrative Procedure Act.

2. Whether governmental hearings on the admissibility of imports are subject to the uniform procedures

expressed in the Administrative Procedure Act.

3. Whether genuine and triable issues of material fact exist, as evidenced by opposing documents submitted in the District Court, which relate to the fitness as food of 3,394 sacks of coffee beans.

STATEMENT

PROCEEDINGS BELOW

This is a suit brought by the petitioner to compel the Food and Drug Officers to allow the import of reconditioned coffee beans so that they may be sold in the United States for the production of blended coffee. The petitioner seeks a decision based upon the exclusive record of an administrative hearing under the authority of §801 of the *Federal Food, Drug and Cosmetic Act*, 21 U.S.C. 381 and §7 of the *Administrative Procedure Act*, 5 U.S.C. 556(e), formerly 1006(d).

The following is a brief account of the background of this case.

The coffee beans in question were being transported from Colombia to Japan in March 1966, when a fire occurred aboard ship. They were watered down with fresh and salt water and unloaded at the distress port of Los Angeles, California. Purchased by the petitioner, the coffee beans were then transported to Turlock, California, where they were cleaned, dried and resacked under the supervision of the U. S. Customs. On July 20, 1966, the petitioner filed for consumption entry at

the Bureau of Customs, San Francisco, offering for import 3,394 sacks of reconditioned coffee beans.

On July 21, 1966, Food and Drug Officer Fred E. Norman issued a Notice of Detention and Hearing (Pet. Exh. A) on the contention that the reconditioned coffee beans were adulterated within the meaning of Section 402(a)(3).

Commencing on August 18, 1966, the petitioner attempted to secure from the FDA the scientific basis for the detention of the coffee beans. The requested information was not provided. (See Pet. Exh. A-1). The petitioner's attorney, after consulting with scientific advisors, felt impelled to continue to press for specific scientific data essential to preparing for a meaningful administrative hearing on the detained coffee beans. However, late in November, the Food and Drug Administration severed further discovery procedures and scheduled the administrative hearing. (Pet. Exh. G-1).

On January 6, 1967, a hearing was held in San Francisco, California, before Food and Drug Hearing Officer Fred E. Norman at which the petitioner appeared and introduced evidence. The FDA refused to offer any evidence at all. The hearing was completed, and the matter was submitted for decision. (Pet. Exh. I-1 and J).

On February 1, 1967, Food and Drug Officer Jack B. Forbragd approved only part of the petitioner's application, allowing said coffee beans to enter the United States to be used in the production of soluble coffee but not in the production of blended coffee. (Pet. Exh. K and L).

On February 15, 1967, the petitioner submitted his application asking reconsideration on the matter of using the said coffee beans in the production of blended coffee. On March 28, 1967, Mr. Forbragd notified petitioner's attorney by telephone and by letter that the latter application was denied. (Pet. Exh. M-O and Def. Exh. IG).

On March 31, 1967, a petition for Writ of Mandatory Injunction to compel the Food and Drug Officers to approve petitioner's application to allow the reconditioned coffee beans to be used in the production of blended coffee in the United States was filed. (IR. 1-10).

On April 19, 1967, the government filed a motion for dismissal of the petition for summary judgment. (IR. 23-88).

On April 20, 1967, petitioner filed a cross-motion for summary judgment. (IR. 14-22).

On May 2, 1967, the District Court heard the petition and motions, (Reporter's Transcript (IIR.)), and on May 16, 1967, the District Court Order was entered dismissing the petition and denying petitioner's said motion and granting the government's motion for summary judgment. (IR. 125).

EFFECT OF THE DECISION BELOW

The specific question of the present action is whether 3,394 sacks of coffee beans should be admitted to the United States. The underlying question, the fundamental issue, is the proper *modus operandi* of a government agency. The appellant respectfully calls to the attention of the present court

the implications of the lower court's decision. The District Court has said in effect that a governmental agency can make import determinations which can have adverse effects--sometimes drastic--on an individual citizen, without basic safeguards:

1) The FDA is *not* required to inform individuals fully as to the basis of its action;
2) The FDA is *not* required to conduct a fair hearing in which both sides state for the record their arguments;
3) The FDA is *not* required to submit the record of a case for judicial review at the behest of an adversely affected individual.

SUMMARY OF ARGUMENT

Basing its arguments upon a particular wording within the Food, Drug and Cosmetic Act composed sixty years ago, the Food and Drug Agency claims that its actions regarding exclusion of imports are unchallengeable because it possesses absolute discretion. The appellant maintains that the intent of Congress, as demonstrated within the Food, Drug and Cosmetic Act, within the Administrative Procedure Act, and by the legislative histories of both acts, was to grant no such power to the FDA. Moreover, the courts actually have reviewed import determinations, creating a precedent strengthened by the passage of the Administrative Procedure Act. Since the passage of this reform act, both the courts and recognized authorities have stated forcefully and specifically that the

safeguards of the APA should be energetically applied regarding FDA regulatory actions. Thus, providing for judicial review and for fair hearings is fundamentally in accord not only with our general legal traditions, but also with contemporary judicial and legislative actions.

Nonetheless, such provision has not clearly been maintained regarding import adjudication procedures. Thus this case inevitably will have far-reaching effects; all industries involved with the importing of food, drugs or cosmetics will be touched by its outcome. It provides an opportunity for extending the uniform procedures governing other administrative activity to cover import adjudications, so that the interests of all--the import industry, the public and the FDA itself--may be upheld. The court will avail itself of this opportunity by reaffirming the precedent for judicial review of import adjudications and by reversing the decision of the lower court.

The District Court's issuance of a summary judgment in the present case confounded the intent of the APA. But even if the APA had not existed, the District Court would still have been in error in granting a summary judgment to the governement because there did exist triable issues of fact. Thus, the appellant respectfully petitions the court to remand the case to the District Court with instructions that provision now be made for a fair hearing or that a trial *de novo* be conducted.

ARGUMENT

I

THE FDA IMPORT DETERMINATION PRESENTLY IN QUESTION IS REVIEWABLE

A. Administrative Procedure Act Was Passed by Congress to Insure Adequate Court Remedy for Individuals.

The making of adjudications is the exercise of authority by an administrative agency wherein the agency acts essentailly as a court, handing down decisions involving the individual parties. Adjudications are the principal method whereby the agency applies the law enacted by Congress to private persons. They involve such matters as granting or withholding licenses, determining law violations, setting individual rates and determining the admissibility of imports.

It is obvious that determinations resulting from the adjudication process can have far-reaching effects on private citizens. Cognizant of this fact, Congress saw fit to pass the Federal Administrative Procedure Act in 1946. Its major objective was to protect individuals from arbitrary actions by government officials. Thus, the act provided that concerned individuals have reasonable access to government information, that hearings be conducted fairly, and that there be provision for judicial review of agency decisions. Upon a showing that an agency was exceeding its jurisdiction, prompt judicial intervention was mandated. The aim in providing these individual protections was not to hamper the workings of any agency; rather it was felt that the passage of the APA would

improve the operation of government agencies by eliciting better administrative decisions.

Two APA provisions clearly proclaiming Congress' intent that judicial review be readily accessible are as follows:

§702, entitled, "Right of Review," says:

> "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."

§704, entitled, "Actions Reviewable," states:

> "Agency action made reviewable by statute and *final agency action for which there is no other adequate remedy in a court are subject to judicial review.*" (Emphasis added.)

B. The Supreme Court Has This Year Ruled That APA Review Provisions Apply to FDA Actions.

In 1956, in *Brownell vs. Wo Shung,* 352 U.S. 180, 185, the Supreme Court stated:

> "...'exemptions from the...Administrative Procedure Act are not lightly to be presumed' and unless made by clear language of supersedure the expanded mode of review granted by the Act cannot be modified."

Now in 1967, the highest court of the land has gone on to apply specifically the review sections of the APA to actions of the Food and Drug Administration. In the *Abbott Laboratories vs. Gardner,* (1967) 387 U.S. 136 and *Toilet Goods Association, Inc. vs. Gardner,* (1967) 387 U.S. 158 decisions, handed down since the decision of the District Court in the present case, it was held that the FDA must follow APA procedures in promulgating regulations. Regarding court sur-

veillance, the court stated:

> "...survey of our cases shows that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress. (Citations)
>
> "Early cases in which this type of judicial review was entertained have been reinforced by the enactment of the Administrative Procedure Act, which embodies the basic presumption of judicial review to one 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute,' 5 U.S.C. 702, so long as no statute precludes such relief or the action is not one committed by law to agency discretion, 5 U.S.C. 701(a). The Administrative Procedure Act provides specifically not only for review of 'Agency action made reviewable by statute' but also for review of 'final agency action for which there is no other adequate remedy in a court,' 5 U.S.C. 704. The legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed that theme by noting that the Administrative Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation. (Citations) Again in *Rusk vs. Cort*, supra, at 370-380, the Court held that only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review. See also Jaffe, Judicial Control of Administrative Action 330-359 (1965)."

Abbott Laboratories vs. Gardner, supra, at 140-141.

The appellant maintains that the determination in question fits easily within the "broad spectrum of administrative actions" that Congress intended be covered by the APA's "generous review provisions." He believes he can demonstrate not only a lack of "'clear and convincing evidence' of a contrary legislative intent" but also positive indications that

Congress did envisage Court protection for individuals in situations comparable to the present.

C. The District Court Erred in Applying The Second Exception of APA 701(a) to The Present Case.

APA Section 701(a) specifies just how broadly the Act's provisions on judicial review are to be applied. It states:

> "This chapter applies, according to the provisions thereof, except to the extent that--
>
> (1) statutes preclude judicial review; or
>
> (2) agency action is committed to agency discretion by law."

The fact that the Food, Drug and Cosmetic Act does not expressly preclude judicial review of import determinations is obvious enough; it is not even contested by the District Court. Instead, the Court relies on the second exemption of APA 701(a) and argues that judicial review is precluded in this case because FDA's actions were "committed to agency discretion by law." An examination of the Food, Drug and Cosmetic Act serves to refute this argument.

1. Internal evidence from the Food, Drug and Cosmetic Act indicates that the FDA lacks absolute discretion regarding import adjudictions.

a. FDA lacks absolute discretion when judging domestic products; criteria for judging imports are the same.

While not denying that FDA does indeed have a burden of proof in domestic seizures, the Court bases its contention that safeguards to the individual do not apply regarding

imports on the argument that the legislature in writing a separate FD&C Act section in imports decreed a totally different procedure for them. Because the separate section 801 states:

> "If it appears from the examination of such samples or otherwise that...such article is adulterated...then such article shall be refused admission..."

The District Court claims that the FDA can make an unchallengeable determination of the fitness of any import product, solely on the basis of its estimation of that product's appearance.

The fact is that Congress did not relegate its instructions regarding the agency's handling of imports to 801. Imports are mentioned all through the Act, and many times it is specified or implied that they are to be treated similarly to domestic products. For example, §304(d)(1) governing seizure actions makes no distinction regarding criteria for judging fitness between food of domestic origin and food imported into the United States. The FDA itself underlined this statement when it chose to cite §402(a)(3), undeniable criterion for domestic products, to condemn the appellant's import product. (See Pet. Exh. A). Inasmuch as criteria for judging food offered for import is the same as that for domestic food, what then, it may be asked, is the purpose of §801? The logical purpose for including §801 is that the District Court could not otherwise obtain jurisdiction over a product offered for import since the product would be outside the United States. The seizure procedure would not be

applicable. There is no evidence that Congress, in making said exclusion procedure applicable by adding §801, intended that the determination procedure be different from that employed in domestic seizures.

b. The FDA lacks absolute discretion when promulgating regulations; logic dictates that if regulations are reviewable, that determinations also be reviewable.

The *Abbott Laboratories* case dealt with §701 of the FDC Act which describes procedures for issuing regulations. §701 clearly covers regulations made relative to the import provisions of §801, and there is no question but that judicial review is guaranteed regarding issuance of import rules. There is no basis for distinction between judicial review of regulations under §801 and of determinations made pursuant to that same section. To hold otherwise would produce absurd consequences and could give vent to the very evil which the APA sought to correct. If it were held that an individual were entitled to judicial review of regulations but not of determinations, then it can be foreseen that the agency could arbitrarily choose to promulgate only a minimal number of regulations, thereby freeing itself of obligation to follow APA procedures. The agency could exercise authority by means of determinations, none of which could come under the scrutiny of the courts. Surely such would defeat the very purpose for which the APA was enacted. Furthermore, considering the inflexibility and definitive nature of regulations as opposed

to the degree of variability of opinion with which determinations are made, common sense decrees that if judicial review is required at all that requirement for determinations should take precedence over that for regulations.

That language of §701 of the FDC Act implies that import adjudications are subject to review.

An underlying assumption that the FDA would in no instance be entirely immune from judicial surveillance manifests itself a number of times within §701. For example, §701(f)(6) states:

> "The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

§701(g) states:

> "A certified copy of the transcript of the record and proceedings under subsection (e) (procedure for holding hearings on proposed regulations) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, *exclusion of imports, or other proceedings arising under or in respect of this Act,* irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f)." (Emphasis and explanation added.)

If hearing transcripts in any "proceedings arising under... this Act," including those regarding exclusion of imports, "shall be admissible," then the implication is certainly that Congress does not preclude the possibility that import adjudications will be reviewed.

2. Analysis of the second exception by recognized authorities supports applicability of judicial review in the present case.

As stated by the Ninth Circuit in *Ferry vs. Udall*, (1964) 336 F.2d 706 at 711, the problem of interpreting APA Section 701(a) "is that of determining when the agency action is 'committed to agency discretion' and when it merely 'involves' discretion which is nevertheless reviewable. 4 Davis, Administrative Law Treatise 28.16 pp. 80-81; Anno:, Administrative Procedure Act, 97 L. Ed. 884, 889."

The authority referred to Professor K. C. Davis, University of Minnesota Law School, has this to say on the subject:[1]

> "A practical interpretation which will carry out the probable intent and which will produce sound substantive results will emphasize the word 'committed' to agency discretion, it is not reviewable, even for arbitrariness, or abuse of discretion; it is not 'committed' to agency discretion to the extent that it is reviewable. The two concepts 'committed' and 'unreviewable' have in this limited context the same meaning. Both depend upon what is committed 'by law' to agency discretion--*both depend upon the statutes and the common law.* To the extent that 'the law' cuts off review for abuse of discretion, the action is committed to agency discretion. The result is that the pre-Act law on this point continues. And the courts remain free, except to the extent that other statutes are controlling, to continue to determine on practical grounds in particular cases to what extent action should or should not be unreviewable even for abuse of discretion." (Emphasis added.)

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[1] Davis, Administrative Law Treatise, 1965 Pocket Part Sections 28.16, pages 15-30 at 21.

Davis' analysis supports the appellant's contention that the FDA's determination under the FDC Act, Section 801, wa not an agency action "committed by law to agency discretion." Davis says reviewability depends upon common law which traditionally *has* afforded judicial review, in regard to Section 801 by virtue of *Ambruster vs. Mellon,* (D.C. Cir. 1930) 41 F. 2d 430 and the *The James J. Hill* (D. Md. 1946) 65 F. Supp. 265. In light of the fact that there is no substantial difference between the present case and the *Ambruster* and *Hill* cases, judicial review as to Section 801 should continue as in the past. It has been held that the judicial review provisions of the APA, at least insofar as availibility of review is concerned, are declaratory of previously existing law. *Olin Industries vs. NLRB* (1947 DC), 72 F. Supp. 225. Judicial review should now be afforded under the principle announced in U. S. ex rel *Trinler vs. Carusi* (C.A. 3d, 1948) 166 F. 2d 457, vacated on other grounds. It was there held that judicial review would not be denied in instances in which it had been traditionally afforded in spite of the language of Section 10 to the contrary.

In the case of *Snyder vs. Buck* (1948 D.C. Dist.Col.) 75 F. Supp. 902, vacated on other grounds (85 App. D.C. 428), the court stated:

> "Subsection (a), Section 10, confers the right to secure a judicial review on any person adversely affected or aggrieved by an agency act within the meaning of any relevant statute. The effect of this provision is, on the one hand, to exclude from the right of judicial reveiw all

governemental action affecting the public generally, but not impinging on the legal right of an individual; and on the other hand, to permit an appeal to the courts by any person whose individual legal rights are adversely affected.

A second recognized authority has the following to say regarding the second exemption:[2]

"The other exception of action 'committed to agency discretion' has, perhaps understandably, created a certain confusion and uncertainty. The further provisions of the judicial review section make it clear that the mere presence of agency discretion does not oust review. Under the heading, 'Scope of Review,' an agency action may be set aside for 'an abuse of discretion' which clearly implies reviewability despite the presence of discretion.

"As one court has said, '...almost every agency action "involves" an element of discretion or judgment....' This is not to be taken as a plea for judicial interference with discretion; the argument is rather that *the presence of discretion should not bar a court from considering a claim of illegal or arbitrary use of discretion.* Occasionally, lower courts have been troubled by the APA discretionary exception. One case, *Hiatt vs. Compagna* (178 F. 2d 42 5th Cir. 1949) affirmed by an equally divided Court (340 U.S. 880 1950) is unusually instructive. *Compagna* was paroled. Unfavourable newspaper publicity led to a Congressional investigation. A new parole board told a Congressional committee that they saw no reason for revoking

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[2] Jaffe, Judicial Control of Administrative Action, 374-375 (1965). See also Schwartz, The Administrative Procedure Act in Operation, 29 New York L. Rev. 1173 at 1246-1247 (1954); Berger, Administrative Arbitrariness and Judicial Review, 65 Col. L. Rev. 55 (1965);"Developments in the Law: The Federal Food, Drug and Cosmetic Act" 67 Harvard L. Rev. 632 at 675, in conjunction with its footnotes 328 and 394 (1954).

> the parole, but on the Committee's request promised to and then did revoke the parole. The Court of Appeals, observing that the provision of the statute 'bristle with discretion,' held the action nonreviewable under the Administrative Procedure Act. Yet it instructed the lower court that if the order was a 'total nullity' the court might in the exercise of its general equity power set the order aside. The district court then called upon the parole board to produce its evidence for revoking the parole, and finding that there was no 'substantial evidence' of parole violation, ordered *Compagna* released. The upshot is that *there are vey few discretions, however broad, substantially affecting the person or property of an individual which cannot at some point come under judicial surveillance...*" (Emphasis by Jaffe)

3. Legislative history indicates that judicial review is available.

The legislative history of the FDC Act underlines the validity of Jaffe's commentary in supplying evidence that Congress did not wish to exclude the possibility of judicial review of agency actions.

Prior to the commencement of lengthy hearings which were to culminate in the passage of the 1938 FD&C Act came the aforementioned *Ambruster vs. Mellon,* supra, the first of two major cases in which a federal court did, in fact, review FDA import adjudications. The District Court did note the existence of this and a second case, the *James J. Hill,* supra, which, as stated above, did provide legal precedent for the appellant's first pleas. However, the District Court chose to discount the value of this legal precedent. First it noted irrelevantly that the petitioner in both cases lost, and then

it claimed that the fact that both cases antedated the passage of the APA (1946) and the decision of *Larson vs. Domestic and Foreign Commerce Corp.*, (1949) 337 U.S. 682, made their validity questionable. The appellant, on the other hand, sees the timing of *Ambruster* and *Hill* as a factor enhancing his claim to judicial review. *Ambruster* occurred in the days of the 1906 Act. Aware that review of an import determination had been undertaken under the old act, Congress could well have added a clause to the 1938 Act excluding such a possibility had it so desired. The fact is that Congress incorporated the old import section into the new law in a form that was in every respect the same, except for very slight changes in some language.[3] Thus it was not surprising that the courts undertook to review the second case, *Hill*, on the validity of an import adjudication after the passage of the new law, whose basic import section, incidentally, Congress has still not seen fit to change twenty-one years later.

That Congress did not take advantage of its opportunities to exclude by statutory provisions the possibility of judicial review in import adjudications is significant. The question

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[3] Modified statement of then Commissioner of Food and Drug Administration, Walter Campbell, before a Subcommittee of the Senate Committee on Commerce on S. 1944, 73rd Cong. 2d Sess. (1933) reprinted in Dunn, *Federal Food, Drug and Cosmetic Act: A Statement of Its Legislative Record* 1102 (1938). This was the extent of the legislative history in regard to import Section 801.

remains, however, of what its motivation was in specifying review procedures for some agency actions and not for others such as import adjudications. Here the *Abbott Laboratories, et al., vs. John W. Gardner,* supra at 141-143, opinion is instructive and worth quoting at length:

> "...we must go further and inquire whether in the context of the entire legislative scheme the existence of the circumscribed remedy evinces a congressional purpose to bar agency action not within its purview. From judicial review as a leading authority in this field has noted: 'The mere fact that some acts are reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent.' Jaffe, *supra,* p. 357.
>
> "In this case the Government has not demonstrated such a purpose; indeed a study of the legislative history shows rather conclusively that the specific review provisions are designed to give an additional remedy and not to cut down more traditional channels of review. At the time the Food, Drug and Cosmetic Act was under consideration, in the late 1930's, the Administrative Procedure Act had not yet been enacted, the Declaratory Judgment Act was in its infancy, and the scope of judicial review of administrative decisions under the equity power was unclear. It was these factors that led to the form that statute ultimately took. There is no evidence at all that members of Congress meant to preclude traditional avenues of judicial relief. Indeed, throughout the consideration of the various bills submitted to deal with this issue, it was recognized that 'there is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law,...(and that) protection is given by the so-called Declaratory Judgment Act....' *H.R. Rep.* No. 2755, 74th Cong. 2d Sess., 8. It was specifically brought to the attention of Congress that such methods had in fact been used in the food and drug area, and the Department of Justice, in opposing the enactment of the special review procedures of Section 701, submitted a memorandum which was read on the floor of the House

stating: 'As a matter of fact, the entire subsection is really unnessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court.' *83d Cong. Rec.* 7892 (1938)."

It can readily be seen that the FD&C Act does not contain the "clear language of supersedure" without which the Supreme Court feels "the expanded mode of review granted by ...(the APA) cannot be modified." *Brownell vs. Wo Shung*, supra at 185.

The appellant concludes argument on his first point, that the FDA action which is the basis of this suit, is without question, subject to judicial review, by quoting the highest court of the land:

"Compare the majority and minority reports on the review provision (Federal Food, Drug and Cosmetic Act), *H.R. Rep.* No. 2139, 75th Cong. 3d Sess. (1938), both of which acknowledged that traditional judicial remedies were available, but disagreed as to the need for additional procedures. The provisions now embodied in a modified form in Section 701(f) were supported by those who feared the life-and-death power given by the Act to the executive officials, a fear voiced by many members of Congress. The supporters of the special review section sought to include it in the Act primarily as a method of reviewing agency factual determinations....

"Some congressmen urged that challenge to this type of determination should be in the form of a *de novo* hearing in a district court, but the Act as it was finally passed compromised the matter by allowing an appeal on a record with a 'substantial evidence' test, affording a considerably more generous judicial review than the 'arbitrary and capricious' test available in the traditional injunctive suit."
Abbott Laboratores, et al., vs. John W. Gardner, et al., supra, at 143.

II

FAIR HEARING PROCEDURES ARE REQUIRED IN THE MAKING OF IMPORT ADJUDICATIONS BY THE FDA

This action was brought by a salvor in order to be relieve of the burden of illegal administrative procedures utilized by the respondents. The appellant contends that he is entitled to a fair hearing under the Administrative Procedures Act and the Food, Drug and Cosmetic Act, and that there is no sound basis for depriving him of his property without affording him said fair hearing.

A. Fair Hearings Are Required By The Administrative Procedures Act.

1. The act's legislative history supports this thesis:

The intent of Congress as manifested by the legislative history of the Administrative Procedures Act establishes the applicability of the hearing provisions to all administrative agencies, including the Food and Drug Administration.

The Administrative Procedures Act was enacted after ten years of exhaustive study and consideration. The Senate Report of 1939 *(S. Rept. No. 442, 76th Cong., 1st Sess.)* is just one of the documents which gives insight into the thinking which underlay its passage. The following portions found on pages 9 and 10 concern the negative effects of the situation then pertaining in which government agencies were not required to conduct hearings according to uniform fair procedures:

> "Unfortunately, the statutes providing for fair hearings before the so-called independent

agencies of the Federal Government, as well as those providing for the conduct of affairs of the single-headed agencies, do not provide for uniform procedure for...hearings or for a uniform method of scope of judicial review. All argument that such uniformity is neither possible or desirable is answered by the fact that uniformity has been found possible and desirable for all classes of both equity and law actions in the court exercising the whole of the judicial power of the Federal Government. It would seem to require no argument to demonstrate that the administrative agencies, exercising but a fraction of the judicial power may likewise operate under uniform rules of practice and procedure and that they may be required to remain within the terms of the law as to the exercise of both quasi-legislative and quasi-judicial power.

"The results of the lack of uniform procedure for the exercise of quasi-judicial power by the administrative agencies have been at least three-fold: (1) the respective administrative agencies give little heed to, and are little assisted by, the decisions of the courts applicable to such agencies; (2) the courts are placed at considerable disadvantage because they must verify the basic statutes of all decisions relating to other administrative agencies which are cited to them, thus slowing up the writing of opinions in particular cases; and (3) individuals and their attorneys are at a disadvantage in the presentation of their administrative appeals, with the result that there is a tendency to emphasize the importance of the judiciary in the administrative process... Furthermore, the statutes, commencing with the Interstate Commerce Act, have made no provision whatever for improvement of the administrative process and rarely have these statutes admitted to prescribe even in a general way, the scope of judicial review. The result has been that the administrative agencies and the courts have been required to work out the procedure from case to case with unnecessary fumbling in the administrative process and with unnecessary criticism of the courts when they have attempted--not altogether with success-- in their decisions to lay down general rules of trial and appellate procedure."

The Attorney General's Committee on Administrative Pro-

cedure, appointed in 1941, stated another representative viewpoint in its proposed administrative act:

> "The exercise of administrative powers, insofar as they affect private rights, privileges or immunities, should be effected by established procedures designed to insure adequate protection of private interest and to effectuate the declared policies of Congress. While procedures should be conducted of the necessities and differences of legislation, and of the subject matter involved, they should, in any event, be made known to all interested persons. Administrative adjudication should be attended by procedures which assure due notice, adequate opportunity to present and meet evidence and argument and prompt decisions."
>
> *Administrative Procedure in Government Agencies Report of the Committee on Administrative Procedure, Appointed by the Attorney General at the Request of the President, to Investigate the Need for Procedural Reform in Various Administrative Tribunals and To Suggest Improvements Therein* (S. Doc. No. 8, 77th Cong., 1st Sess., dated January 22, 1941).

One of the concerns brought out during the House Proceedings was as follows (*House Committee on the Judiciary, House Report No. 1980*, May 3, 1946):

> "Manifestly, the bill does not unduly encroach upon the needs of any legitimate government operation, although it is, of course, operative according to its terms, even if it should cause some administrative inconvenience or change in procedure...functionally, classifications and exemptions have been made, but in no part of the bill is an agency exempted by name. The bill is meant to be operative 'across the board' in accordance with its terms, or not al all..."

It would seem to be altogether apparent that the intent of Congress was to regulate the so-called "fourth branch" of government for the purpose of safeguarding individual rights.

Its goal was to assure judicial fairness, tantamount to that guaranteed by the U.S. Constitution, in the government agency adjudication process. Its means of carrying out its intent was to provide that hearings be conducted in accordance with standards similar to those utilized by the judiciary.

The appellant maintains that he should have been afforded such a hearing during the adjudication out of which this action arises.

2. Case law supports liberal interpretation of the Administrative Procedure Act.

In the *Japanese Immigrant Case* (1903) 189 U.S. 86, 191, the Supreme Court commented that requirements of procedural due process are derived from the same source as Congress' power to legislate, and where applicable, permeate every valid enactment of that body. The Court stated:

> "....In the case of all acts of Congress, such interpretation ought to be adopted as, without doing violence to the import of the words used, will bring them into harmony with the Constitution."

In both *Pan-Atlantic S.S. Corp. vs. Atlantic Coast Line R. Co.*, (1956) 353 U.S. 436, and *Wong Yang Sung vs. McGrath*, (1949) 339 U.S. 33, the court became more specific in terms of the present case. It declared that the APA is a remedial and reform piece of legislation, and, as such, should be liberally construed. The *Wong* case, which will be more fully discussed presently, involved the legitimacy of a deportation order under the Immigration Act and the right of the aggrieved party to a hearing in accordance with the provisions of the

APA. The Supreme Court concluded that the APA provisions affording hearings should be liberally construed.

3. The District Court erred in determining that an exception in §554(a) precludes fair hearings in import adjudications.

The appellant maintains that the FDA should have made the adjudication required by the Food, Drug & Cosmetic Act, Section 801, according to the terms of Administrative Procedure Act, Sections 554, 556 and 557. On this point, the District Court's argument is that these sections are not applicable due to the following wording contained in Section 554(a):

> "This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing."

Since the FD&C Act, Section 381, does not contain a provision expressly requiring an adjudication to be determined "on the record," the District Court feels that all three APA sections are inapplicable.

Let us examine a Supreme Court case revolving around these very words of APA 554(a). In the aforementioned *Wong Yang Sung vs. McGrath*, supra, it will be remembered that the issue was the legitimacy of a deportation order when the immigration authorities had not given Wong a fair hearing according to APA standards.

In *Wong*, there were more statutory barriers to the application of Sections 554-7 than in the present case. Not only

did the Immigaration Act fail to provide that the adjudications be decided on the record after a hearing, but it also failed to mention that a hearing be held at all. Section 801 of the FD&C Act does specify that a hearing be held when it instructs the FDA to "give notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education and Welfare and have the right to introduce testimony."

Because of case law rather than statutory requirements, immigration authorities did hold deportation hearings in actual practice. The manner in which they were conducted by immigration authorities, prior to the *Wong* case, was the same as that in which hearings on the admissibility of imports have been conducted by the FDA, i.e., immigrants threatened with deportation were simply given an opportunity to speak on their own behalf.

The Supreme Court ruled that this procedure was inadequate for the protection of individual rights. In light of the fact that court decisions had added hearings to deportation proceedings, it dismissed the barriers that the Immigration Act itself required neither hearings nor that determinations be based upon the record. Thus, lacking the statutory support available in the present case, Wong nevertheless won his case.

It should be pointed out that the Supreme Court was not unmindful of the effects which its decision would have on the government agency involved. In this respect, *Wong*, supra, stated:

> "Nor can we accord any weight to the argument that to apply the Act to such hearings will cause inconvenience and added expense to the Immigration Service. Of course it will, and as it will to nearly every agency to which it is applied, but the power of the purse belongs to Congress and Congress has determined that the price for greater fairness is not too high. The agencies, unlike the aliens, have ready and persuasive access to the legislative ear and if error is made by including them, relief from Congress is a simple matter."

After the decision by the United States Supreme Court that the APA applies to deportation hearings, immigration authorities did indeed go to Congress. They subsequently secured a fair procedure for deportations, modeled on pertinent portions of the Administrative Procedure Act but adapted to the particular needs of the deportation process. As far as we know, the FDA has not chosen to take comparable steps. In light of the clear dictum of the *Wong* case, the appellant maintains that the agency should be governed by the APA until it does.

4. The District Court erred in determining that an exception in §554(a)(3) precludes fair hearings for import adjudications.

The government, pursuing its point that adjudication under the FD&C Act, Section 801, is not subject to APA rules, cites APA 554(a)(3). This provision excludes from the general hearing requirements cases which involve "proceedings in which decisions rest solely on inspections, test or elections." As an aid to interpreting these words, rules of statutory construction should be applied.

As noted above, a remedial statute such as the APA is entitled to liberal construction. *(Abbott Laboratories vs. Gardner,* supra.) The corollary principle is that such statutes are to be strictly construed. Thus, a proviso which operates to limit the application of the provision of the statute should be held to include no case not clearly within the purpose, letter, or express terms of the proviso. *(Piedmont & N. R. Co. v. Interstate Commerce Commission* (1932) 286 U.S. 299; *Gregg Cartage & Storage Co. v. United States* (1942) 316 U.S. 74.)

The exemption dealing with inspections and tests has been interpreted by the Supreme Court in just such a strict manner. Exemption has been confined to instances in which there are explicit, definitive standards, such as those of the Tea Importation Act, to be applied. (See discussion of Tea Importation Act below.) In the case of *Door v. Donaldson,* 195 F. 2d 764 (1952), the court stated as follows:

> "In our opinion the act exempts from the requirements of a full hearing, because they 'rest solely upon inspections,' only decisions that turn either upon physical facts as to which there is little room for difference of opinion, or else upon technical facts like the quality of the tea...."

Quite obviously the present circumstance is not within the purview of this exception. There was no definitive, explicit standard for judging the coffee, nor was the determination made upon physical facts as to which there was "little room for difference of opinion." The government *a fortiori* did not even draw upon the standards set by the coffee industry

itself in determining the quality and fitness of the product. On the contrary, the decision as to fitness was based admittedly upon a subjective examination by various personnel within the agency, whose thoughts, opinions and determinations were not based upon any standard procedure, rules or regulations.

In reviewing the cases mentioned above, it can be seen that the higher courts have consistently reaffirmed the intent of Congress, in its passage of the Administrative Procedure Act, by applying APA hearing provisions in the interest of individual protection. The appellant maintains that the District Court erred in failing to follow this precedent.

B. Fair Hearings Are Required by the Federal Food, Drug and Cosmetic Act.

1. An analysis of its pertinent provisions in the light of rules of statutory construction bears out this contention.

Section 801 specifies that an import adjudication be made only after the owner of the goods in question is given notice, an opportunity to appear before a representative of the Department of Health, Education and Welfare, and the right to introduce testimony. The procedure described is certainly tantamount to a hearing, and certain rules of statutory construction compel the conclusion that this terminology of Section 801 is to be construed to mean a hearing.

In the interpretation of statutes, some degree of implication traditionally may be called upon to aid the discovery of the intention of the legislature. *(Mercantile Trust Co.*

v. Road Dist. (1927) 275 U.S. 117.) That which is implied from the express terms of a statute is as much a part thereof and is as effectual as that which is expressed. *(Luria v. United States* (1913) 231 U.S. 9.) Moreover, in the absence of a contrary indication, legislative enactments which are prospective in operation and which are couched in general and comprehensive terms apply to new situations which arise. *(Feitler v. United States,* (CA-3, 1929) 34 F.2d 30; *Buck v. Jewell-LaSalle Realty Co.,* (1931) 283 U.S. 191.) According to these three rules, Section 801 constitutes a basis upon which a fair hearing is to be granted. The language implies a hearing, and the appellant will presently support his contention that a hearing is what Congress had in mind. But even if Congress, in enacting these procedures with respect to notice, opportunity to appear, and the right to introduce testimony, did not specifically envisage a "hearing," the language is prospective in nature and is broad enough to include the new situation which, in this particular case, is the hearing now afforded by and provided for by the APA.[4]

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[4] The FDA itself ascribes to these rights, the word, "hearing". It sent to the importer a form entitled, "Notice of Hearing". In this respect, a rule of statutory construction maintains that the Executive Department charged with the administration or enforcement of such rules of procedure is entitled to the highest respect. *(United States v. Bergh* (1956) 352 U.S. 40.) If the FDA itself deems this language to mean a hearing, then the appellant believes the court should acknowledge its interpretation.

Other rules of statutory construction further confirm the premise that Section 801 of the FDC Act requires a hearing. The legislature is presumed to have enacted a statute directed toward achieving a just result. *(Washington Terminal Co. v. Boswell* (1941) 124 F.2d 235, (affirmed in 319 U.S. 732); *United States v. City National Bank of Duluth* (1939) 31 F.Supp. 530.) It is not presumed to have intended to provide for the performance of a vain, idle or futile act, nor to produce an absurd consequence. *(United States v. American Trucking Associations* (1940) 310 U.S. 534, rehearing denied 311 U.S. 724; *Armstrong Paint and Varnish v. Nu-Enamel Corporation* (1938) 305 U.S. 315.) Furthermore, that construction of a statute which affords an opportunity to evade an act should be avoided, and conversely, construction which would defeat subterfuges or evasions of the intent of the statute is to be favored. *(Scarborough v. Atlantic Coast Line R. Co.* (1949) (CA 4th Va.) 178 F.2d 253.) Let us look at Section 801 in terms of these ground rules. It would seem that the intent of Congress in suggesting that the importer be given an "opportunity to introduce testimony" could be only its desire to assure that the importer's rights were not infringed upon in an arbitrary manner. Yet how is the protection of the importer's rights to be guaranteed if the agency is allowed simply to disregard the testimony if it so chooses? The agency's listening to but totally ignoring the case presented by the importer is a quite possible, but vain, unjust and absurd consequence of an interpretation which deems that Section

801 does not imply a fair hearing with the determination made on the record.

Still another rule of statutory construction is that the court will strive to avoid an interpretation of a statute which produces capricious distinction or discrimination between situations which are not substantially different. *Talbott v. Silver Bow County* (1890) 139 U.S. 438; *Wilson v. Federal Communications Comm.* (1948 C.A.D.C.) 170 F.2d 793. To formulate separate, distinct hearing rules with respect to the promulgation of regulations and the making of adjudications is to promote a senseless distinction. Logic demands we recognize that there is no sound reason why a hearing should be granted in one instance and not in the other. The safeguards provided by the APA in the form of a hearing should apply in each instance. If anything, there is greater need for the right to a hearing with respect to the adjudicatory function, for, in the final analysis, adjudicatory decisions must be based upon a subjective analysis of the evidence as presented.

2. The District Court erred in determining that an FDC Act provision precludes fair hearings in import adjudications.

(a) It improperly emphasized a single phrase rather than interpreting the Food, Drug and Cosmetic Statute in its entirety.

The District Court erred in virtually ignoring the

pertinent portions of Section 801 just analyzed and in relying almost exclusively on other language in that section, to wit:

> "If it appears from the examination of such samples or otherwise that....(3) such article is adulterated...then such article shall be refused admission...."

It is an elementary rule of statutory construction that significance and effect should be accorded every part of an act. *(United States v. Alpers* (1950) 338 U.S. 680; *D. Ginsberg & Sons v. Papkin* (1932) 285 U.S. 204.) The maxim, *ut res magis quam perat* requires not merely that a statute be given effect as a whole, but that effect should be given to *each* of its express provisions. *(Pennsylvania Co. v. United States* (1915) 236 U.S. 351.) Further, all parts of the act should be considered, compared and construed together. It is not permissible to rest a construction upon any one part alone or upon isolated words, phrases, clauses or sentences. *(Hellmich v. Hellman* (1928) 276 U.S. 233; *International Mercantile Marine Co. v. Lowe* (1938) (CCA 2d) 93 F.2d 663 (writ of certiorari denied in 304 U.S. 565.) In addition, each statute or section is to be construed in light of, with reference to, and in connection with other statutes or sections. *(Textile Mills Securities Corp. v. Commissioner of Internal Revenue* (1941) 314 U.S. 326.)

A Federal Court reiterated these maxims in *U. S. v. 88 cases, etc...Bireley's Orange Beverage* (1946) 5 F.R.D. 503, where it was held that the Federal Rules of Civil Procedure applied to the FD&C Act after this analysis:

"In interpreting the statute in question we must look to the entire statute and not to the single phrase."

In applying these rules of statutory construction, it is elementary that undue emphasis cannot, as the government would wish it, be placed upon a sentence or phrase which may appeal to a particular party. The language of the statute which deals with notice, opportunity to appear, and the right to introduce testimony must be considered in conjunction with the language which states that if it appears from the examination of a sample or otherwise that such article is adulterated then such article shall be refused admission. The two are entitled to equal weight, and, if at all possible, are to be interpreted so as to give effect to both. In this regard, it is consistent and logical to construe the two pertinent portions of Section 801 to mean the following: that a person is entitled to a hearing and entitled to a determination based upon a record, and that if a person does *not* desire to avail himself of these privileges, then, *and only then*, may the government exclude the particular article offered for import "if it appears from a sample or otherwise that the article is adulterated....". The words, "or otherwise" are of particular importance here and lend credence to the interpretation which appellant contends is logical and consistent. The "or otherwise" provides for cases where there is a controversy, and in which a hearing has been in fact requested and conducted. This interpretation is, in fact, the only interpretation that does not do violence to the pertinent

portions of Section 801 and does not unduly emphasize one section over the other.

(b) The District Court mistakenly ascribed Tea Inspection Act standards to the FDC Act.

In rejecting the necessity for a fair hearing in the present case, the District Court relied heavily upon *Buttfield v. Stranahan,* (1903) 192 U.S. 470, which involved an administrative refusal to admit into the United States a shipment of tea found by a Board of General Appraisers to be below certain standards set by the Secretary of the Treasury. The District Court mistakenly applied the principles in *Buttfield v. Stranahan* to invest the FDA with completely discretionary powers. However, an examination of the two separate acts upon which *Buttfield* and the present case rest, i.e., the Tea Inspection Act and the Food, Drug and Cosmetic Act, shows that they are quite distinct from each other.

The Tea Importation Act was enacted in 1897 and provides that the government, upon recommendation by a board of experts, shall fix and establish uniform standards of purity, quality and fitness for consumption of all kinds of teas imported into the United States. The quality of any tea in question shall be tested and graded according to the usage and customs of the tea trade, including the testing of an infusion of the same in boiling water and, if necessary, chemical analysis. The Food, Drug and Cosmetic Act, on the other hand, does not require the government to set standards and grades for coffee, and the government thus has not done so. If, however, there

were such a requirement, the importer then could challenge these coffee standards under the statutory procedures of the FD&C Act, Section 701 or the Administrative Procedure Act. However, even in the Tea Importation Act, there is a specific statutory procedure for a fair hearing, and, in matters of dispute, access to decision review by the U. S. Board of Tea Appeals.

(c) The District Court ignored specific wording which indicates an assumption that fair hearings will be part of the adjudication process.

Section 701 (e)(1) states in part:

> "Any action for the issuance, amendment, or repeal of any regulation under Section 401, (concerns definitions and standards for food), 403 (j) (concerns misbranding), 404(a) (concerns emergency permit control), 406 (concerns tolerances for poisonous ingredients in food), 501(b), or 502(d) or (h) (concerns drugs) shall be begun... (a procedure is then specified for putting the action into effect.)"

Section 701(e)(2) continues:

> "...any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, ...requesting a public hearing upon such objections."

Section 701(c) says:

> "Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as may be designated for the purpose."

Section 701(g) reads as follows:

> "A certified copy of the transcript of the record and proceedings under sub-section (e) shall be furnished by the

> Secretary to any interested party... and shall be admissible in any criminal libel for condemnation exclusion of imports, or other proceeding arising under or in respect of this Act...."

The impact of these provisions on the present case can be stated succinctly as follows: transcripts of hearings dealing with such matters as the promulgation of regulations fixing food standards "shall be admissible" at exclusion of import proceedings. The appellant feels it is highly significant that the writers of the law eschewed such language as "can be presented." Wording such as that might be seen as being consistent with the FDA's interpretation as to the character of the hearing authorized in Section 801. The language which actually was used is of a totally different character. "Shall" is imperative, not permissive. "Admissible" is a technical legal term, defined as follows in *Black's Law Dictionary,* 4th ed.:

> "Pertinent and proper to be considered in reaching a decision. Used with reference to the issues to be decided in any judicial proceedings.
>
> As applied to evidence, the term means that it is of such a character that the court or judge is bound to receive it; that is, allow it to be introduced."

The appellant maintains that the wording of Sections 701(e), (c) and (g) constitutes ample evidence that the import exclusion hearing proceeding envisaged by the enactors of the law is not an empty formality, in which the hearing officer can listen in patronizing fashion to an aggrieved party but is free to ignore what is said. On the contrary, the hearing

officer "is bound to receive" transcripts and other admissible evidence. Does this not clearly imply that a fair hearing is to be held, the rules for which have since been specified by the Administrative Procedure Act?

III

THE DISTRICT COURT ERRED IN GRANTING A SUMMARY JUDGMENT

A. Its Decision Was Contrary to the Intent and Provisions of the APA.

Professor Davis, supra, at page 27-28 of his 1965 Pocket part, inquires:

> "Is it good government--is it sound law--that permits a single individual to determine issue of law, fact, and discretion, affecting the property rights....., without hearings, without review, without disclosure of the rules that are used to guide discretion, and without opening to public inspection the resulting law?"

In affirming that the District Court erred in granting the FDA a summary judgment in the present case, the appellant respectfully commends to the Appellate Court Professor Davis' answer to his own question:

> "A review court, without at any point substituting judgment, could (a) determine the reasonableness of the rules developed by the administrator as a guide to discretion, (b) require that those rules be open to public inspection, (c) ascertain whether the particular exercise of discretion arbitrarily departs from the administrative case law, (d) require that the administrative case law be open to public inspection in compliance with §3(b) of the Administrative Procedure Act, (e) require findings of fact and a statement of reasons, (f) determine whether the findings are supported by substantial evidence, (g) determine whether the stated reasons are based upon considerations which are reasonable and legal."

1. The District Court should have exercised the authority to review agency actions given it by the APA.

APA Section 10(e) 5 U.S.C. 701(e), entitled, "Scope of Review," provides:

> "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning of applicability of the terms of an agency action. The reviewing court shall--
>
> 1) compel agency action unlawfully withheld or unreasonably delayed; and
> 2) hold unlawful and set aside agency, action, findings, and conclusions found to be--
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance or procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial *de novo* by the reviewing court.
>
> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of prejudicial error."

The law thus clearly invests the District Court with the

power to "set aside agency action." The appellant proposes to show that the court should have acted on this power, on the grounds that the FDA's adjudication was made "not in accordance with law" and that it was "unsupported by substantial evidence."

2. The District Court should have reviewed the issues of law involved.

In *U. S. vs. 449 cases...Tomato Paste,* (C.C.A. 2d 1954) 212 F.2d 567, concerning an allegedly adulterated product from Portugal which had been seized within the United States, the dissenting opinion of Justice Frank included the following admonition to his peers:

> "Our responsibility goes beyond the adjudication of the validity of the legislative grant. It includes the duty of scrutinizing the methods employed in the process of administrating the granted power. Unless this power is in some way constrained (as I believe it has been by the Administrative Procedure Act) it permits dangerous administrative arbitrariness...."

The appellant shares both Justice Frank's concern regarding the methods employed in the process of administrating the granted power and his belief in the efficacy of APA safeguards.

(a) The FDA deprived petitioner of information to prepare for a hearing.

The APA emphasizes in provision after provision that government agencies are to make full disclosure of matters pertaining to adjudications. APA, Section 556, states:

> "The transcript of testimony and exhibits, together with all papers and requests filed

in the proceeding, constitutes the exclusive record for decision in accordance with Section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties."

APA, Section 557(c)(3), says in part:

"All decisions, including initial, recommended, and tentative decisions, are a part of the record and shall include a statement of--

(A) findings and conclusions and, the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record."

APA Section 554(b) says:

"Persons entitled to notice of an agency hearing shall be timely informed of--

(3) the matters of fact and law asserted."

Section 552(d) deals with access to Public Records:

"Except as otherwise required by statute, matters of official record shall be made available, in accordance with published rule, to persons properly and directly concerned..."

In addition, the FDA's own regulation, 21 CFR 4.1(c) entitled "Disclosure of Official Records and Information," states:

"A person who desires the disclosure of any such record or information may make written request therefor, verified by oath, directed to the Commissioner of Food and Drugs, setting forth his interest in the matter sought to be disclosed and specifically designating the use to which such records of information will be put in the event of compliance with such request..."
(Pet. Exhibit "D" and "E".)

The importance of reasonable access to government information has been further expressed in the Public Information

Act of 1966 (Public Law 89-487) which amended Section 552 of the APA. Under this legislation, executive agencies are required to adopt new guidelines to insure full disclosure of information affecting individuals.

Compare these numerous provisions with the actual methods of operation employed by the FDA.

On July 21, 1966, the FDA issued a "Notice of Detention and Hearing" on the grounds that the coffee beans in question were adulterated. The basis for the alleged adulteration was stated as follows: "The article is unfit for food since the beverage made from it after roasting is nearly devoid of flavor and color characteristics of normal coffee."

Almost any commercially-sold coffee is composed of a blend of more than one type of coffee, the purpose of mixing coffees being to enhance flavors and to satisfy varying consumer preferences. Naturally-bitter coffees are balanced by being blended with naturally-mild types. Thus, there is a genuine usefulness for many varieties of coffee beans which would be too strong or too weak by themselves.

The owner of the coffee beans in question consulted with food scientists who gave as their opinion that the product had value as a food when used as an element in blended coffee. Since the government had decreed otherwise, the owner felt that he needed access to data concerning the objective criteria by which the government had judged the product to be unfit. Lacking such information, he could not make a meaningful preparation for the hearing.

Thus, from August 18, 1966, until the "hearing" on January 6, 1967, the owner's attorney attempted to secure from the FDA information concerning the scientific basis for the detention of the coffee beans. One of the answers, as contained in Petitioner's Exhibit "C" typified the rest:

> "We are also unable to comply with your broad request for copies of all of our analyses and related reports pertaining to this detention and hearing. However, we can advise you that our Bureau of Science examined a beverage made from this coffee after roasting and found it to be nearly devoid of the flavor and color charactertistics of normal coffee. In view of this, we consider this coffee to be unfit for food within the meaning of section 402(a)(3) of the Act, a copy of which is attached. May we also direct your attention to Chapter VIII of the Act (page 75), on Imports and Exports."

The Supreme Court in *Simmons vs. United States* (1955) 348 U.S. 397 at 405, commented on another situation in which a government agency had not disclosed information in accordance with APA procedures, as follows:

> "A fair resume is one which will permit the registrant to defend against the adverse evidence--to explain it, rebut it, or otherwise detract from its damaging force... The Congress, in providing for a hearing, did not intend for it to be conducted on the level of a game of blind man's bluff..."

(b) FDA disregarded fact-finding procedures.

The Supreme Court in *Green vs. McElroy* (1958) 360 U.S. 474 at 496-497, expressed the following general principles:[6]

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[6] See also *Kirby vs. Shaw* (CA-9, 1966) 358 F.2d 446; Cooper, "Should Administrative Hearing Procedures Be Less Fair Than Criminal Trials (1967) 53 ABAJ 237.

"Certain principles have remained relatively immutable in our jurisprudence. One of these is that where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue. ...We have formalized these protections in the requirements of confrontation and cross-examination...This Court has been zealous to protect these rights from erosion. It has spoken out not only in criminal cases (citations), but also in all types of cases where administrative and regulatory actions were under scrutiny (ctiations). Nor, as it has been pointed out, has Congress ignored these fundamental requirements in enacting regulatory legislation ..."

To continue with the chronology of the FDA's actions: At the "hearing" on January 6, 1967, the Government presented no evidence that the coffee beans in question were adulterated. The hearing officer dismissed this essential element required for a fair hearing in the beginning, as follows: (Petitioner's Exhibit "I-1", page 13):

"MR. MC KRAY (Attorney for petitioner): Now, at this hearing, is the Food and Drug Administration going to present any evidence?

THE HEARING OFFICER: No. We are here to hear what you have to say."

After the petitioner presented his evidence for the record, the petitioner's attorney questioned the procedure for said hearing as follows, (Petitioner's Exhibit "I-1", pages 52-53):

"MR. MC KRAY: But the issue is that this hearing should comply with the fundamental principles of fair play, principles of fair play with the facts involved in the case.

I would like to point out at this time that

the Food and Drug Administration made no presentation at this hearing, nor has the Food and Drug Administration allowed the owner or consignee to examine any record or document involved in said coffee.

The second thing I would like to point out is this: Are you going to make the decision in this matter?

THE HEARING OFFICER: First, I would like to point out that we presented our position when we issued the Notice of Detention and Hearing, and this hearing is for the purpose of your presenting your position.

In answer to your second question, no, I probably will not make the decisiion. It will be probably be made in Washington.

MR. MC KRAY: Washington, D.C. will make the decision?

THE HEARING OFFICER: Yes."

The last exchange quoted has special significance in the light of APA §554(d):

"The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency..."

On this matter the appellant cites *Steward vs. Penny*, (1965) 238 F. Supp. 821 at 827:

"We cannot, however, accept without limitation a contention that a high administrative official in Washington, D.C., is better qualified than others to analyse and draw conclusive fact inferences from a cold record produced at an evidentiary hearing three thousand miles away and relating to physical conditions with which he has questionable familiarity, conditions normally deemed to be within the realm of judicial notice. We deem the correct rule of judicial review to be that announced in *Foster vs. Seaton*, (1959) 106 U.S. App. D.C. 253, 271 F. 2d 836: 'Thus the case

> really comes down to a question whether the secretary's findings were supported by substantial evidence on the record as a whole.' This is the only rule of judicial review which will breathe vitality into the mandate of Congress (Administrative Procedure Act, 5 U.S.C., Section 1009(e)..) that the reviewing court shall 'hold unlawful and set aside agency actions, findings and conclusions found to be:
>
> (1) Arbitrary, capricious and an abuse of discretion or otherwise not in accordance with law;...
>
> (4) Without observance of procedure required by law;
>
> (5) Unsupported by substantial evidence in any case subject to requirements of Section 1006 and 1007 of this title or otherwise reviewed on the record of the agency hearing provided by statute....'"

The ninth circuit has also held that these administrative decisions must be based on hearing records having "a reasonable basis in law, and . . . are supported by substantial evidence." *Stockton Port District vs. Federal Maritime* (1966) 369 F. 2d 380 at 381.

3. In accordance with APA provisions which require decisions to be made upon the record, the District Court should have granted a summary judgment to the petitioner rather than to the government since there were no triable issues of fact. The FDA's import determination was unsupported by substantial evidence. APA 556(d) says in part:

> "A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts therof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence."

The appellant asks the court to examine the evidence

presented by the government at the "hearing." As summarized by the FDA hearing officer, ("... we presented our position when we issued the Notice of Detention and Hearing...."), the government's evidence consists of the statement: "Adulterated within the meaning of Section 402(a)(3). The article is unfit for food, since beverage made from it after roasting is nearly devoid of flavor and color characteristics of normal coffee."

APA 556(d) opens as follows:

> "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof."

The appellant feels that without the burden of proof, the FDA's evidence is insufficient, and that with the burden of proof, it is impotent.

B. Even Without Consideration of APA Provisions Summary Judgment Should Not Have Been Granted the Government Because There Were Triable Issues of Fact.

In the instant case the District Court held that it did not have authority to review an FDA import determination. It did note *Ambruster v. Mellon and James J. Hill*, supra, allowing import determinations under the wording of Section 801 of the 1938 FD&C Act to be tried *de novo*. However, the District Court claimed that the fact that both cases antedated the passage of the APA (1946) made their validity questionable.

Since the District Court's deicision, the U. S. Supreme Court in another case involving the FD&C Act has given quite another interpretation as to the effect of the APA's passage

on earlier case law. It said:

> "...early cases in which this type of judicial review was entertained (citations) have been *reinforced* by the enactment of the Administrative Procedure Act...."
>
> *Abbott Laboratores v. Gardner,* supra, at 141. (Emphasis added.)

Thus, regardless of whether specific APA provisions are considered, early case law would seem still to be very much in effect and to decree that petitioners are indeed entitled to a trial *de novo.*

Let us consider the action which the District Court did take, however, i.e., the granting of a summary judgment to the government.

It is well established that a summary judgment should be granted only if there is no issue which calls for a trial. Rule 56(c) *Federal Rules of Civil Procedure; Fountain v. Filson* (1949) 336 U.S. 681; *Simler v. Conner* (1963) 372 U.S. 221 and *Poller v. Columbia Broadcasting System Inc.* (1962) 368 U.S. 462.

Following are a number of judicial commentaries on the subject:

In *Homan Mfg. Co. v. Long* (C.A. 7 - 1957) 242 F. 2d 207, it was held that a summary judgment proceeding was not a substitute for a trial but rather a judicial search for determining whether genuine issues exist as to material facts.

A summary judgment motion does not involve the trial of issues of fact but is rather in the nature of a preliminary

proceeding to ascertain whether or not there are genuine issues as to a material fact. *Burgert v. Union Pac. R. Co.* (C.A.8-195 240 F.2d 207 and *Dulansky v. Iowa-Illinois Gas & Elec. Co.*, (C.A.8-1951) 191 F. 2d 881.

The Court examines evidence on a motion for summary judgment, not to decide any issue of fact but to discover whether any real issue exists. *Ramsouer v. Midland Valley R. Co.*, (C.A 8-1943) 193 F.2d 318.)

In this action, the District Court was considering defendants' motion and a separate petitioner's motion for summary judgment. As verified above, its primary duty was to decide whether or not there were any facts which would give rise to a triable issue, not to pass upon or determine the issue itself. If that were not true, controversial issues of facts would be tried upon affidavits by the court and not by a jury. Here a triable issue of fact was present. It was provided by the original notice of hearing, to wit, WHETHER THE RECONDITIONED COFFEE BEANS WERE FIT FOR FOOD. The District Court, contrary to precedent, decided this issue of fact without a trial *de novo*. (IR. 22-26.)

The opposing declarations stated the triable issue, whether the reconditioned coffee beans are fit for food. The exhibits offered by both sides support the opposing contentions. Government's Exhibit 1 is offered in support of the negative position. Petitioner's Exhibit "I-1" (Reporter's Transcript of Administrative Hearing on January 6, 1967) and Petitioner's Exhibit "J" (Summary Report: "Quality of Recon-

ditioned Coffee," dated January 3, 1967) provide positive evidence that the reconditioned coffee beans are fit for food. Since there was a triable issue of fact, the District Court was then powerless to proceed further but should have allowed such issue to be tried by a jury unless a jury trial was waived.

The appellant takes issue not only with the outcome of the proceedings below, but with the procedure leading to the outcome.

First, the District Court ignored the petitioner's right to cross-examine witnesses and basic rules of evidence. (IIR. 2-9). Secondly, the District Court accepted Government Exhibits 1, 2, 3 and their respective subsections, although these exhibits were prepared by the FDA *after* the administrative hearing (IIR. 27-31).

The acceptance of Exhibits 2 and 3 is objectionable on other grounds in that they dealt with the condition of the coffee beans prior to their being offered for importation as reconditioned coffee beans. These exhibits are irrelevant and immaterial in determining whether the said reconditioned coffee beans are fit for food according to the reasoning given in *James J. Hill*, supra, at 269:

> "By Section 381 the Collector of Customs was authorized to refuse admission if the article was 'adulterated.' By Section 342 'a food shall be deemed to be adulterated...(3) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food....'. We may put aside in this case the words filthy and putrid,

> but it is the contention of the government that the damaged wheat was decomposed and otherwise unfit for food. There was substantial evidence, and indeed it is not disputed by the plaintiff, that there was some decomposition in the wet wheat and to some extent at least it was fermented and moldy.
>
> ...(however) it is important here to distinguish between the condition of the grain, when first offered for importation, and its condition after it had been dried. And it is also very important in this connection to note that there is really no controversy between the parties whether the wet grain before the drying was unfit for food of any kind, animal or human. In its original wet condition it was...so unfit for any kind of food. The controversy...as to its fitness for food is thus limited as to whether after being dried it was fit...."

Thus the appellant contends that the District Court erred in granting the government's motion for summary judgment. Instead appellant affirms that the District Court should have granted a trial *de novo* on the "Complaint and Petition for Writ of Mandatory Injunction" (IR 1-7).

CONCLUSION

The appellant's pleas are as follows:

1. The judgment of the District Court be reversed and the case remanded to the District Court.

2. Procedural guidelines be designated to provide the petitioner with a *fair hearing* to determine whether the reconditioned coffee beans are fit for food.

The appellant offers for the Court's consideration a variety of procedural paths designed to procure an equitable

outcome of the present case:

1. Under the Administration Procedure Act, allow the reconditioned coffee beans to enter the United States to be used for the production of blended coffee as supported by the administrative hearing record (Petitioner's Exhibit "I-1"). After the goods have been released from the physical custody of Customs, they will be subject to the domestic seizure provisions of the FD&C Act if the FDA still does not approve their importation. *230 Boxes of Fish v. United States* (C.A.6-1948) 168 F.2d 361. If a seizure action does occur, the petitioner will be entitled to a fair trial in the District Court.

2. Remand the case to the FDA for a determination of the substantive issue by an administrative hearing conducted in accordance with the provisions of the Administrative Procedure Act.

3. Remand the case to the District Court for a determination of the substantive issue by a trial *de novo*.

The entire import industry dealing with foods, drugs, and cosmetics will be affected by this decision. Clearly, administrative hearings conducted without procedural safeguards can be dangerous. The primary purpose of this appeal is to request the reviewing court to protect private rights, by stipulating that fair hearing procedures be used and reasonable access to government information be assured. The application of such procedures should serve to further the interests both of the individual and society, in that better

and fairer administrative decisions should result.

Dated: January 5, 1968, San Francisco, California.

Respectfully submitted,

GEORGE McKRAY and
SHELDON I. BLAMAN

GEORGE McKRAY

By _____
George McKray
Attorneys for Appelants.

STATE OF CALIFORNIA]
] No. 22,102
City and County of San Francisco]

I certify that, in connection with the preparation of this brief, I have examined Rules 18, 19 and 39 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

GEORGE A. McKRAY

George A. McKray
Attorney for Appellant

AFFIDAVIT OF SERVICE BY MAIL

STATE OF CALIFORNIA]
] No. 22102
City and County of San Francisco]

ROBERT L. JOHNSON, being duly sworn, says: That he is a citizen of the United States, over 18 years of age, not a party to the within action. This affiant's business address is 1255 Post Street, Suite 625, San Francisco, California. That affiant served copies of the attached APPELLANT'S OPENING BRIEF, on each of the following at their respective addresses by placing said copies in envelopes addressed as follows:

Cecil F. Poole
U. S. Attorney
Robert N. Ensign
Assistant U. S. Attorney
450 Golden Gate Avenue
San Francisco, Calif.
(3) copies

Arthur Dickerman, Esq.
FDA District Office
1521 W. Pico Blvd.
Los Angeles, Calif. 90015
(3) copies

which envelopes were then sealed and postage fully prepaid thereon, and thereafter were on January 5, 1968, deposited in the United States Mail at San Francisco. That there is delivery service by United States mail at the places so addressed, or regular communication by United States mail between the place of mailing and the places so addressed.

ROBERT L. JOHNSON

Robert L. Johnson

Subscribed and sworn to before me
this 5th day of January, 1968.

GRACE G. HACKETT

Grace G. Hackett, NOTARY PUBLIC
In and for the City and County of
San Francisco, State of California
My commission expires Feb. 9, 1971.

APPENDIX

I

STATUTES

Administrative Procedure Act, 60 Stat. 243 (1946) as amended, 5 U.S.C. §§ 552-558, 701-706 (1966)

§ 552. (formerly §1002) *Publication of information, rules, opinions, orders, and public records*

(c) Each agency shall publish, or in accordance with published rule, make available to public inspection all final opinions or orders in the adjudication of cases (except those required for good cause to be held confidential and not cited as precedents) and all rules.

(d) Except as otherwise required by statute, matters of official record shall be made available, in accordance with published rule, to persons properly and directly concerned, except information held confidential for good cause found.

§ 554. (formerly § 1004) *Adjudications*

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved--

(1) a matter subject to a subsequent trial of the law and the facts de novo in a court;

(3) proceedings in which decisions rest solely on inspections, tests, or elections;

(b) Persons entitled to notice of an agency hearing shall be timely informed of--

(1) the time, place, and nature of the hearing;

(2) the legal authority and jurisdiction under which the hearing is to be held; and

(3) the matters of fact and law asserted.

(c) The agency shall give all interested parties opportunity for--

(1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and

(2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title.

(d) The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not--

(1) consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or

(2) be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply--

§ 556. (formerly §1006) *Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision*

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence--

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more hearing examiners appointed under section 3105 of this title.

* * * * *

The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and on payment of lawfully prescribed costs, shall be made available to the parties. When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

§ 557. (formerly §1007) *Initial decisions; conclusiveness review by agency; submissions by parties; contents of decisions; record*

(a) This section applies, according to the provisions thereof, when a hearing is required to be conducted in accordance with section 556 of this title.

(b) When the agency did not preside at the reception of the evidence, the presiding employee or, in cases not subject to section 554(d) of this title, an employee qualified to preside at hearings pursuant to section 556 of this title, shall initially decide the case unless the agency requires, either in specific cases or by general rule, the entire record to be certified to it for decision.

(c) Before a recommended, initial, or tentative decision, or a decision on agency review of the decision of subordinate employees, the parties are entitled to a reasonable opportunity to submit for the consideration of the employees participating in the decisions--

(1) proposed findings and conclusions; or

(2) exceptions to the decisions or recommended decisions of subordinate employees or to tentative agency decisions; and

(3) supporting reasons for the exceptions or proposed findings or conclusions.

The record shall show the ruling on each finding, conclusion, or exception presented. All decisions, including initial, recommended, and tentative decisions, are a part of the record and shall include a statement of--

(A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record; and

(B) the appropriate rule, order, sanction, relief, or denial thereof.

§ 558. (formerly §1008) *Imposition of santions; determination of applications for licenses; suspension, revocation, and expiration of licenses*

(b) A sanction may not be imposed or a substantive rule or order issued except within jurisdiction delegated to the agency and as authorized by law.

§ 701. (formerly §1009) *Application; definitions*

(a) This chapter applies, according to the provisions thereof, except to the extent that--

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

§ 702. (formerly §1009(a)) *Right of review*

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

§ 703. (formerly §1009(b)) *Form and venue of proceeding*

The form of a proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. (formerly §1009(c)) *Actions reviewable*

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

§ 705. (formerly §1009(d)) *Relief pending review*

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

§ 706. (formerly §1009(e)) *Scope of review*

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

Food, Drug and Cosmetic Act, 52 Stat 1055 (1938) as amended, 21 U.S.C. § 381, 371 and 334 (1966)

CHAPTER VIII--IMPORTS AND EXPORTS

Sec. 801 [381]. (a) The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. . . . . If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is

exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional times as may be permitted pursuant to such regulations. . . .

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article of the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health, Education, and Welfare that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an office or employee of the Department of Health, Education and Welfare designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

CHAPTER VII--GENERAL ADMINISTRATIVE PROVISIONS

Regulations and Hearings

Sec. 701 [371]. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such

manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable gounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. . . . .

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. . . .

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, exclusion of imports, or other proceeding arising under or in respect of this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

Sec. 304 [334] (Seizure provision)

(d)(1) . . . . If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(d) can and will be met: *Provided, however,* That the provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a) (1), (2), or (6), section 501(a)(3), section 502(j), or section 601(a) or (d); *And provided further,* That where such exportation is made to the original foreign supplier, then clauses (1) and (2) of section 801(d) and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(d) have been met.

II

REGULATIONS

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act §§ 1.318-1.320, 20 Fed. Reg. 9539 (1955) as amended at 30 F.R. 5507 (1965); § 4.1(c), 20 Fed. Reg. 15285 (1964).

§ 1.318 *Hearing.*

(a) If it appears that the article may be subject to refusal of admission, the chief of district shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the chief of district shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1.319 *Application for authorization.*

Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1.320 *Granting of authorization.*

(a) When authorization contemplated by § 1.319 is granted, the chief of district shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the Bureau of Customs, as the case may be,

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the chief of district may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the chief of district.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 4.1 *Disclosure of official records and information.*

(c) A person who desires the disclosure of any such record or information may make written request therefor, verified by oath, directed to the Commissioner of Food and Drugs, setting forth his interest in the matter sought to be disclosed and specifically designating the use to which such records or information will be put in the event of compliance with such request. . . .